

REMARKS

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 3-21, 23-38, 40-76, 78-83, 87-89, 93 and 99-122 are pending in this application. Claims 65-68 are withdrawn from consideration and the remaining pending claims are currently under examination

Claim 5 has been amended to indicate an additional solvent can be added to water. Claims 87-89 have been amended to delete the reference to prevention. The applicants reserve the right to pursue cancelled subject matter in a continuation or divisional application. No new matter has been added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE 35 U.S.C. 112, 1st PARAGRAPH REJECTION HAS BEEN OVERCOME

Claims 87-89 were rejected as allegedly lacking enablement for the full scope of the invention. This rejection has been rendered moot by the cancellation of the term “prevention” claims 87-89.

III. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME

A. Claims 1, 3-21, 23-38, 40-64, 73-76, 78-83, 87-89, 99-112, 117-119 and 122 were rejected as allegedly being obvious over Hochrainer et al. (U.S. Patent 6,150,418) in view of Blondino et al. (U.S. Patent 6,004,537) or Carling et al. (U.S. Patent 5,674,860).

B. Claims 69-72 were rejected as allegedly being obvious over Hochrainer et al. (U.S. Patent 6,150,418) in view of Blondino et al. (U.S. Patent 6,004,537) or Carling et al. (U.S. Patent 5,674,860) and further in view of the PDR.

C. Claim 93 was rejected as allegedly being obvious over Hochrainer et al. (U.S. Patent 6,150,418 - "Hochrainer") in view of Blondino et al. (U.S. Patent 6,004,537) or Carling et al. (U.S. Patent 5,674,860) and further in view of the PDR.

D. Claims 113-116, 120 and 121 was rejected as allegedly being obvious over Hochrainer et al. (U.S. Patent 6,150,418) in view of Blondino et al. (U.S. Patent 6,004,537) or Carling et al. (U.S. Patent 5,674,860) and further in view of the Hardman et al. (*Goodman & Gilman's The Pharmacological Basis of Therapeutics*) or Leckie et al. (Novel Therapy of COPD).

The applicants request reconsideration of these rejections for the reasons cited in the preliminary amendment of 18 January 2006 (which can be considered incorporated here by reference) and for the summary of those arguments which follow below.

Genus-species relationship between present invention and U.S. Patent 6,667,344

The '344 patent is also assigned to Dey L.P. and was filed on the same day as the present application.

During the telephonic interview of January 10, 2006, the applicants' representative indicated that the claims of the '344 patent were generic to the claims of the present invention, i.e. the claims of the '344 patent introduced the inventive concept that it was possible to have formoterol in aqueous solution and achieve long term stability.

The composition claims of the '344 patent used "comprising" language which allowed for the possible inclusion of other ingredients as long as it did not affect the inventive concept of formoterol in aqueous solution with long term stability.

The present invention is a species of the '344 genus, i.e. the inclusion of other possible ingredients in the present invention must specifically include "a steroid anti-inflammatory agent, or a pharmaceutically acceptable salt or hydrate thereof".

U.S. Patents are presumed to be valid

The genus claims of the '344 patent had also been rejected with the Hochrainer reference, but these rejections were withdrawn and the genus claims were allowed. As all U.S. Patents are presumed to be valid (35 U.S.C. § 282), it is incongruous that the broader genus claim is allowable over Hochrainer and additional references, but the narrower species claim is obvious over the essentially the same references. For this reason alone, the applicants' claimed invention is unobvious over the Hochrainer rejections.

Reasonable expectation of success necessary to combine references

The Office Action acknowledges that Hochrainer does not teach each and every element of the applicants claimed invention and additional references have been added to supplement the deficiencies of Hochrainer. However, it is well known that it is insufficient merely to obtain the requisite elements for combination; there must be some teaching, suggestion or motivation to make the combination.¹ The reasons proffered in the Office Action for combining the references do not have any basis from the references themselves or from what was known in the art at the time the applicants' invention was made.

First, the state of the art was that it was expected that an aqueous solution would hydrolyze formoterol and as such use of aqueous solutions was not thought to be a viable option for formoterol containing compositions with expectations of long-term stability as claimed by the applicants. This is illustrated not only within the Hochrainer reference itself but in other references (e.g. U.S. Patent 6,719,994). This point has never been refuted and as such one ordinary skill in the art would not have had a reasonable expectation of success necessary to combine or modify the references.

Second, supporting an obviousness rejection based on "optimization of ranges" (MPEP 2144.05 (section I)) also requires that the particular parameters must first be recognized as a result-effective variable. However, there is no direction from any of the references or from within the state of the art that the formoterol concentration was a results effective variable and certainly not in the context of combination with aqueous solutions.

For this reason alone, the applicants' claimed invention is unobvious over the Hochrainer reference as there was no reasonable expectation of success for modifications or optimization of ranges suggested in the Office Action at the time the invention was made.

¹ "It is well known that 'virtually all [inventions] are combinations of old elements...Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat patentability of the claimed invention. Such an approach would be 'an illogical and inappropriate process by which to determine patentability.'" *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998)(citations omitted).

Obviousness is an “as a whole” determination

Determinations of obviousness requires “as a whole” consideration of both the applicants’ claims and the references cited. see MPEP 2141. Moreover, establishing and maintaining an obviousness rejection requires that a preponderance of the evidence supports a *prima facie* holding of obviousness. During the course of prosecution, the applicants have provided numerous arguments, references in support of their position and a declaration from the applicant which rebutted the presumptions of obviousness.

When a reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, ***the entire merits of the matter are to be reweighed***. *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986).² However, each of applicants’ arguments and pieces of evidence appear to have been addressed individually rather than having the entirety of the rejection being reconsidered in light of the applicants rebuttal and evidence.

When considering the additive effects of the applicants’ current and past arguments and evidence presented against the Hochrainer rejections, the preponderance of the evidence does not support a *prima facie* holding of obviousness.

Conclusion

For any of the above reasons, the applicants claimed invention is not obvious over any of the rejections with Hochrainer.

² “When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker ***must start over***. . . . ***An earlier decision should not***, as it was here, be considered as set in concrete, and applicant’s rebuttal evidence then ***be evaluated only on its knockdown ability***. Analytical fixation on an earlier decision can tend to provide that decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, ***not against the conclusion itself***. . . . [A] final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached by an earlier board upon a different record.” *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,
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